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K024283 510(k) Summary

CardioDirect

November 19, 2002

1. Submitter Information

Name: Reynolds Medical Ltd.

Address:

1 Harforde Court
John Tate Road
Hertford, Herts SG13 7NW
ENGLAND
Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: December 11, 2002

2. Name of Device

Trade Name: CardioDirect
Common Name: 12-Lead Digital Electrocardiograph
Classification name: Electrocardiograph

3. Equivalent legally-marketed devices.

- Reynolds CardioCollect, K013367
- H&C Cardiette, K002074
- GE Mac 5000, K014108
- Spacelabs Burdick Quest Exercise Stress System, K011339
  This system also includes automatic interpretation.

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4. Description

CardioDirect is a 12-lead digital electrocardiograph with interpretation of the electrocardiogram based on a standard personal computer. It can also be used for a stress test if purchased with the proper interfaces. CardioDirect, when used as an electrocardiograph, has a special interface unit between the external connections (ECG electrodes, treadmill and blood-pressure device) and the computer. It permits either manual or automatic interpretation of electrocardiograms.

5. Intended Use

The use of CardioDirect is indicated when it is desired to record and interpret an electrocardiogram of a patient. This includes a resting electrocardiogram, a rhythm electrocardiogram, or a stress electrocardiogram (such as might be taken during an exercise stress test).

6. Performance Data

(a) Non-clinical tests

1. AAMI EC11 tests
2. Validation tests
3. ISO 60601-1, ISO 60601-1-2

(b) Clinical tests

Clinical tests are not necessary since CardioDirect uses the same technology as the predicate device.

(c) Conclusions

CardioDirect is equivalent in safety and efficacy to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Reynolds Medical Ltd.
c/o George H. Myers, Sc.D.
President
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K024283
Trade Name: CardioDirect Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: May 2, 2003
Received: May 5, 2003

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K024283

Indications for Use Form

Device Name: CardioDirect

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use**
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024283